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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,734	11/20/2003	Nam-Tae Woo	DE-1539	1826

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David A. Einhorn, Esq.
Anderson Kill & Olick, P.C.
1251 Avenue of the Americas
New York, NY 10020

EXAMINER

FEDOWITZ, MATTHEW L

ART UNIT PAPER NUMBER

1623

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/718,734

Applicant(s)

WOO ET AL.

Examiner

Matthew L. Fedowitz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 9-48 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/20/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-48 are pending in this action.

Claim Objections

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112 - First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-20 and 28-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 9, 11-12, 14-20 and 28-41 are directed to a method of treating or preventing cancer. The term cancer is interpreted to include any and all forms of cancer that are characterized by angiogenesis as well as the specific locations of cancers as in the stomach, liver, lung, cervix and breasts. In light of this, it can be asserted that in spite of the vast expenditure of human and capital resources in recent years, no one drug has been found which is effective in treating all types of cancer because it is not a simple disease, nor is it even a single disease, but a

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complex of a multitude of different entities, each behaving in a different way. In re Hozumi, 226 USPQ 353 (ComrPats 1985).

Moreover, the determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the factual considerations. In re Wands, 8 USPQ2d 1400 (CAFC). There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include but are not limited to:

1. The breadth of the claims;
2. The nature of the invention;
3. The state of the prior art;
4. The level of one of ordinary skill;
5. The level of predictability in the art;
6. The amount of direction provided by the inventor;
7. The existence of working examples; and
8. The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Wands Analysis

1. The Breadth of the Claims.

The breadth of the instant claims are seen to encompass compounds or pharmaceutical compositions and photodiagnostic and treating agents for the treatment or prevention of all forms

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of cancers as well as methods for the treatment or prevention of cancer that are characterized by way of reproducing singlet state oxygen radicals and superior cell cytotoxicity. The claims are drawn to preventing or treating specific locations of cancers found in the stomach, liver, lung, cervix and breasts. Moreover, the term "treatment" is interpreted as encompassing the alleviation of symptoms associated with the disease or disorder, or stopping the further progression or worsening of those symptoms as well as prevention or prophylaxis of the disease or disorder. The term "prevention" is interpreted as preventing the beginning of any cancerous growth or uncontrolled growth of cells in any individual or mammal.

2. The Nature of the Invention.

The nature of the invention is the treatment or prevention of cancer as well as photodiagnostically imaging cancer through the use of the claimed compounds, pharmaceutical compositions and derivatives thereof. Currently, there are no known agents that treat cancers all inclusively. Additionally, the claims drawn to "a method of photodiagnostic various cancers," will be construed as intending to mean photodiagnostically imaging various cancers.

3. The State of the Prior Art.

The applicant has submitted several patents in order to demonstrate the state of the prior art on January 16, 2003. A close reading of the prior art does not reveal that the art claimed recognizes compounds similar or analogous to those with the ability to treat or prevent cancer. In addition the applicant has submitted one experimental example to determine the anticancer activity of present compounds. This example shows only the use of a breast cancer cell line.

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Though the applicant has demonstrated through example that there may possible anticancer activity in breast cancer cell lines, this does not demonstrate anticancer activity broadly in all forms of cancer or in other locations of the human or mammalian anatomy. Therefore, the example only shows that the state of the art to the extent of the form of cancer mentioned.

4. The Level of Ordinary Skill

In this case, it is important to determine the level of skill in the art at the time at which the applicant claims priority, that being January 16, 2003. The level of skill is that of one with a doctoral understanding of cancer therapeutics.

5. The Level of Predictability in the Art

The treatment of cancer is highly unpredictable due to the differing forms of cancerous cells, their location, their potential for metastases, the fact that cancer therapeutics is palliative rather than curative and that cancer treatment readily harms normal tissues (see Katzung pp. 881-882).

6. The Amount of Direction Provided by the Inventor

The applicant has not demonstrated sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or reference to the same in the prior art to provide a skilled artisan with sufficient guidance to practice the instant treatment or prevention of cancer claimed or photodiagnostically imaging cancer. For example, the applicant only discloses that dosages should be in a therapeutically effective amount.

7. The Existence of Working Examples

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 27 USPQ2d 1510 (CAFC). The disclosure does not demonstrate sufficient evidence to support the applicant's claim to the treatment of cancer. There are not sufficient representations in the disclosure or data from references of the prior art to provide a nexus between those examples and a method of treating or preventing cancer with the claimed compound other than the claimed compound having anticancer activity in breast cancer cell lines.

8. The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

In order for there to be a method of treating or preventing cancer generally, as claimed by the applicant, it would be necessary to show that a vast range of different types of cancers can be treated that have differing cell types, locations and potentials for metastases. Furthermore, direction, in the form of examples, must be shown to determine what a therapeutically effective dose may be. The references submitted do not demonstrate this. Therefore, one of ordinary skill in the art would require a significant amount of experimentation in order to determine the effective dosage to treat or prevent or photodiagnostically image the multitudes of different types of cancer with the claimed compounds, pharmaceutical compositions and photodiagnostic

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imaging agents individually or in combination with other therapeutic agents (See Katzung pp. 882-884).

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 3, 5, 7, 9, -48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A. Claim 3 states that “A is -CH₂-“ however, Structure II of claim 3 does not contain A. Claims 5 and 7 displays A₁ on the compound structure shown yet do not state what A₁ is. Claim 5 also states that R₄ is a hydrogen atom or a hydroxyl group, however, the compound structure shown does not contain R₄. Claim 7 displays R₄ on the structure shown yet does not state what R₄ is.
- B. Claims 9, 11-20 and 28-48 use of the phrase “of the compound of formula (I) to (VII) as set in Claim X” where X is 1-8. These claims are indefinite because formulas (I) to (VII) refer to compounds in separate claims and not compounds found within individual claims as the applicant has set forth. For example, claim 1 does not contain formula (VII). As a result, these claims are indefinite for not particularly pointing out and distinctly claiming the subject matter which applicant regards as the invention.

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- C. Claims 9, 11, 14-20 and 28-34 use the phrase “superior cell cytotoxic activity” without defining what this phrase is in the specification. This phrase has no known meaning in the art and, as a result, renders the claims in which it is found indefinite.
- D. Claims 12, 13 and 35-48 use the phrase “therapeutically effective amount” without defining an amount or even a range of what a therapeutically effective amount is in the specification. As a result, it is unknown what a therapeutically effective amount is and there the claims containing this phrase are indefinite.
- E. Claims 13, 28-34 and 41-48 use the phrase “a method of photodynamic diagnostic various cancers.” The verb/noun agreement in this phrase is unusual and does not makes sense, therefore, rendering the claims indefinite as to their meaning.
- F. Claims 10 and 21-27 are also rejected for being indefinite as they depend from a rejected base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, and 6 are rejected under 35 U.S.C. 102(a) as being anticipated by Hynninen *et al.*, Wasielewski *et al.* and Holt.

As relating to claim 1, Hynninen *et al.* teach the compounds claimed by the applicant (see scheme 1 on p. 4056 compound 15). As relating to claim 4, Wasielewski *et al.* teach the

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compounds claimed by the applicant (see p. 1970 figure 1 subset 1d). As relating to claim 6, the A. S. Holt article teach the compounds claimed by the applicant (see p. 440 figure 1 top under "unstable" chlorine diester).


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew L. Fedowitz whose telephone number is (571) 272-3105 and can be reached between 9am-5:30pm (EST) M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew L. Fedowitz, Pharm.D., J.D.
November 9, 2004



James O. Wilson
Supervisory Patent Examiner
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